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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/815,528	03/23/2001	Roger D. Kamm	0492611-0375 (MIT-8802)	5331
7590 10/05/2004			EXAMINER	
C. Hunter Baker, M.D., Ph.D. Choate, Hall & Stewart 53 State Street Exchange Place Boston, MA 02109			MATHEW, FENN C	
			ART UNIT	PAPER NUMBER
			3764	
DATE MAILED: 10/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,528

Applicant(s)

KAMM ET AL.

Examiner

Fenn C Mathew

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,32 and 34-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30,32 and 34-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The declaration filed on 06/28/2004 under 37 CFR 1.131 is sufficient to overcome the Lewis (U.S. 6,620,116) reference.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-30, 32, 34-35, 41-46, 55-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa (U.S. 5,437,610) in view of Waldrige (U.S. 6,179,796). Cariapa teaches a method including attaching a compression device to a body part of a patient suffering from a disease characterized by low blood flow (circulatory disease), and applying graded sequential pressure (col. 7, lines 14-23) using the compression apparatus. Cariapa does not teach maximum pressure in the claimed range, however, Waldrige teaches an analogous device used for similar treatment, and discloses that pressures up to 255 mm Hg can be used, which fall within the claimed range of the applicant. Therefore it would have been obvious to one having ordinary skill in the art to provide a maximum pressure in the claimed ranges.

Art Unit: 3764

4. Referring to claim 2, Cariapa does not explicitly disclose a method of promoting wound healing, however the use of compression to facilitate wound healing is well known in the art and would have been obvious to the skilled artisan.

5. Referring to claims 3-8, 12, and 14-18, the modified Cariapa device discloses the claimed structural limitations as well as the claimed method steps. Applicant has claimed functions of performing those method steps, therefore it would have been obvious to the skilled artisan that the claimed effects would take place.

6. Referring to claims 9-11, the modified Cariapa device teaches pressure ranges within the claimed pressure ranges. It would have been obvious to one of ordinary skill in the art to choose specific pressure ranges based on suitability for treatment of specific diseases.

7. Referring to claims 19-21, the modified Cariapa teaches the device attached to a user's extremity such as the leg or arm.

8. Referring to claims 22-25, the modified Cariapa teaches the use of fluid filled bladders.

9. Referring to claim 26, as best understood, the modified Cariapa shows a flexible band.

10. Referring to claim 27-30, the modified Cariapa teaches the device used for circulatory diseases. Specific diseases such as peripheral vascular, coronary, artery, and cardiovascular, and diabetes are known to be treated by compression methods. Therefore the treatment of these specific diseases would be obvious to one of ordinary skill in the art.

11. Referring to claims 32 and 34, the modified Cariapa device discloses methods for treating a disease including attaching an apparatus and delivering positive and negative pressure to a body part of a patient, and applying graded sequential pressure. Although Cariapa does not specifically mention wound healing, the method steps are performed using a device of claimed structural limitation.

12. Referring to claims 35, Cariapa teaches a hydraulic system including sequentially compressible bladders (figs. 1-2) being attached to a body part of a patient. Cariapa also teaches the use of graded sequential pressure. (See above cited portions.) Cariapa fails to teach the claimed pressure ranges. Walldridge teaches pressure ranges including the claimed pressure ranges, and furthermore teaches that the device is useful for treating edema (col. 1, lines 23-27). Therefore it would have been obvious to one skilled in the art at the time of invention to utilize pressures in the range of Walldridge in order to treat disease.

13. Regarding claims 41-43, note the withdrawal pump (28) and reservoir (30).

14. Regarding claims 44-46, Cariapa teaches a VELCRO (94) mounting means or control means) but lacks buttons, snaps, elastic bands, or zippers. The feature of choosing different mounting means such as buttons, snaps, elastic bands, or zippers is considered as an obvious design choice since such mounting means are well known in the art.

15. Referring to claims 55-61, limitations drawn to specific speed ranges of waves, time periods for sequential compression, and pressure differences between the distal and proximal regions are considered matters of obvious design choice well within the

Art Unit: 3764

knowledge of the skilled artisan, as the skilled artisan would choose parameters based on suitability for the intended function of treating a specific condition or disease.

16. Claims 35-39, 40, 44, 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng (U.S. 5,997,540) in view of Cariapa and Walldridge. Zheng teaches a device having a plurality of sequentially inflatable balloons (col. 8, lines 39-42), and a computer 7. In column 5, lines 15-24 and column 14, lines 22-24, Zheng discloses a blood oxygen detector, pulse oximeter and blood pressure detector. Zheng further discloses cooling means (21) and a mounting means within the cuff for mounting the cuff to the body (figure 4C). Zheng fails to teach the specific maximum pressures and graded sequential pressure. Cariapa teaches the desirability of graded sequential pressure in an analogous device. Furthermore Walldridge teaches pressure ranges including the claimed pressure ranges. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device of Zheng with graded sequential pressure as taught by Cariapa in order to limit constriction in more sensitive areas (i.e. groin) while providing heavier pressure in areas better capable of receiving such pressure (i.e. ankles) as taught by Walldridge in order to reduce injury while maintaining peak effectiveness. Furthermore, the desired pressure ranges used would also be obvious to the skilled artisan as the skilled artisan would choose appropriate pressure ranges based on their suitability for the disease being treated. Additionally, use of different pressure sources is also notoriously old and well known, and would be obvious to one of ordinary skill. Referring to claim 39, it is notoriously old

Art Unit: 3764

and well known that it is advantageous to provide an EKG detection mechanism in order to correlate sequential pressure based on a patient's heart waves.

Response to Arguments

17. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Peeler et al. U.S. 5,575,762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3764

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

fcm

fcm

October 3, 2004

JR

**JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**

10/3/04